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The Advent of Gene Patenting: Putting the Great Debate in Perspective

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I. INTRODUCTION

Genetic engineering has changed, and will continue to change, the world in which we live. Human beings can now directly manipulate the characteristics and structure of other organisms' genes. This practice can be used for socially beneficial purposes, such as genetically modifying agriculture to increase its resistance to viruses and decrease the need for pesticides or herbicides, thereby generating a higher crop yield. Genetic modification has also led to many advances in medicine, including the creation of synthetic human insulin and the ability to treat a host of genetic disorders. Other scientific breakthroughs have been achieved using genetic engineering as well. Phillip Leder and Timothy Stewart, two Harvard medical researchers, genetically modified mice to carry an oncogene, increasing the susceptibility to cancer and making the animal ideal for cancer research.[1] Upon this event, the United States Patent and Trademark Office ("PTO") issued the first patent for a transgenic animal on April 12, 1998.[2] In 1999, Peter Beyer and Ingo Potrykus discovered that beta-carotene could be produced in rice by introducing two transgenes (phytoene synthase and bacterial carotene desaturase) not found in the original rice compound.[3] The result, "Golden Rice," has the capabilities of providing the recommended daily allowance of vitamin A to many children in developing countries,[4] creating a solution for the half a million children who are at risk of becoming blind annually due to vitamin A deficiency.[5] In May 2001, genetic engineering allowed a woman suffering from infertility due to mitochondrial defects to have children with the help of a donor cell.[6] StemCells, Inc., a biotechnology firm based out of

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1. Douglas Hanahan, Erwin F. Wagner & Richard D. Palmitter, *The Origins of Oncomice: A History of the First Transgenic Mice Genetically Engineered to Develop Cancer*, 21 GENES & DEV. 2258-70 (2007), *available at* http://genesdev.cshlp.org/content/21/18/2258.full#ref-list-1.
2. U.S. Patent No. 4,736,866 (filed June 22, 1984).
3. Golden Rice, The Science Behind Golden Rice, http://www.goldenrice.org/Content2-How/how1_sci.html (last visited Jan. 17, 2009).
4. *Id.*
5. George Ansstas, M.D. et al., *Vitamin A Deficiency*, eMEDICINE, June 16, 2008, http://emedicine.medscape.com/article/126004-overview.
6. Dr. David Whitehouse, *Genetically Altered Babies Born*, BBC NEWS, May 4, 2001, http://news.bbc.co.uk/1/hi/sci/tech/1312708.stm.

Palo Alto, California, transplanted human stem cells into the brains of mice in an attempt to cure neurodegenerative diseases.[7] In January 2009, a study from the Thomas Jefferson University's Center for Transitional Medicine indicated that long-term gene therapy improved the cardiac function of rats with heart failure.[8] There is a steady progression in the uses of gene therapy that is culminating in its increased use in human medicine and agriculture.

All of these scientific advances have an additional common denominator aside from the use and development of genetic science. Underlying each of these discoveries is a patent that protects the holder's claim or process. Moreover, the patent owner has the ability to exclude others from making, using, or selling the patented gene(s) within the United States.[9] Currently, there is a fierce debate concerning the ability of biotechnology and pharmaceutical companies' ability to obtain gene patents. Part II of this article briefly outlines some historical highlights of biotechnology and gene patents and provides a background for understanding the current debate. Part III explores the arguments advanced by both sides and identifies some underlying assumptions and misconceptions regarding those arguments. Lastly, part IV discusses the legal and ethical implications that have resulted from the current patent scheme as it relates to genetic engineering. The primary objective of this article is to put the controversial topic of human gene patenting into perspective. By analyzing the positions of both sides, greater clarity and understanding can be obtained and the ethical and legal implications can be more concretely examined. Additionally, this article aims to put to rest many of the misunderstandings that exist regarding gene patenting.

Scholars have noted that the definition of what constitutes a gene patent is unclear.[10] Although the phrase "gene patent" implies that the patent is issued regarding a specific gene, this article uses the phrase in a broader sense. A gene patent can refer to a specific gene sequence, a sequence of DNA, the usage of the gene sequence, or its chemical composition.

Before delving into the development of biotechnology and the arguments surrounding gene patents, it is useful to identify what is not within the scope of this article. First, this article does not discuss the development of the patentability of genetic inventions. While the appropriateness of patenting nucleotide sequences is vehemently debated, the official position of the

7. Veterinary Sciences Tomorrow, *A Question of Chimeras*, May 10, 2005, http://www.vetscite.org/publish/items/002211/index.html.

8. Veterinary Sciences Tomorrow, *Gene Therapy Reverse Heart Damage in Rats with Heart Failure*, Jan. 13, 2009, http://www.vetscite.org/publish/items/004954/index.html.

9. 35 U.S.C.A. § 271(a) (2009).

10. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239-40 (2005), *available at* http://www.sciencemag.org/cgi/content/full/310/5746/239?ijkey=BRQjr6YEKddW6&keytype=ref&siteid=sci.

PTO is clear. As long as the invention meets the requirements of a patent (novelty, utility, and non-obviousness), the substance, use, and derivatives of the DNA can be patented.[11] Furthermore, many different aspects of genetic inventions are claimed in the patent applications. Partial DNA sequences, such as expressed sequence tags ("ESTs") and single-nucleotide polymorphisms ("SNPs"),[12] uses of genetic sequences, tests for specific genetic diseases,[13] and proteins encoded by genes and their functions,[14] are all patentable. However, the treatment of genes, and their associated applications, as patentable material has not always been recognized; there have been many obstacles to overcome in order to achieve the current patentability status.[15] Second, this article does not deeply explore or explain the chemistry behind many of the gene patents. Due to the extremely complex and technical nature of biotechnology, many of the inventions are difficult to describe in a brief manner. Therefore, the focus of this article will be on the implications of the patents and not on the specific patents themselves.

This article proposes that the patent system is a necessary evil in order to effectively protect the intellectual property inherent in the genetic engineering process. The utilitarian view, a view that considers and weighs the risks and benefits of the practice and subsequently decides whether or not society will benefit as a whole, is the strongest perspective through which to view the debate. While deontological arguments have a place in deciding how the practice should be regulated, arguments that focus solely on the rightness of an action as determined by its consequences, and conclude that genetic patenting should be banned based on moral wrongness deserve less attention. Many of the arguments proposed against gene patents rely on theories that have not been substantiated by research or misconceptions about the rights a patent confers. However, opponents do raise legitimate concerns that must be considered and balanced when deciding if reform is necessary. Furthermore, this article suggests many improvements and identifies areas in need of further research.

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11. 35 U.S.C.A. §§ 101-03 (2009).

12. U.S. Patent App. 20,090,024,401 (filed May 10, 2007).

13. U.S. Patent No. 7,407,756 (filed Mar. 4, 2005) (patenting method for detecting mutations associated with familial dysautonomia).

14. U.S. Patent No. 7,479,368 (filed July 30, 2002) (patenting an isolated nucleic acid molecule comprising a sequence encoding an atypical protein kinase C interacting protein).

15. *See generally* Diana A. Villamil, *Redefining Utility in Determining the Patentability of DNA Sequences*, 5 J. MARSHALL REV. INTELL. PROP. L. 238 (2006).

II. The Historical Development of Gene Patents: Putting the Debate in Context

The biotechnology industry emerged in the 1970's due to a new recombinant DNA technique.[16] In 1973, Herbert Boyer and Stanley Cohen reported the construction of functional organisms that combined and replicated genetic information from different species.[17] Essentially, Boyer and Cohen are credited with discovering and demonstrating recombinant DNA processes.[18] Then, in 1980 the Supreme Court vastly expedited the advent of gene patenting by holding that genetically modified Eubacteria constituted patentable subject matter.[19] The Court construed the language of 35 U.S.C. § 101 broadly, citing legislative history as evidence that a liberal construction should be provided.[20] In 1980, Congress amended title 35 of the United States Code to articulate the policy objectives and goals of the patent system. The statute states:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms and federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to insure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the government obtained sufficient rights in federally supported invention to meet the needs of the government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.[21]

This law, the Bayh-Dole Act (hereinafter the "Act"), was a government initiative to promote commercial development of new technologies and fur-

16. BIO, *Biotechnology Industry Facts*, http://www.bio.org/speeches/pubs/er/statistics.asp (last visited Jan. 18, 2009).

17. Genome News Network, Genetics and Genomics Timeline, http://www.genomenewsnetwork.org/resources/timeline/1973_Boyer.php (last visited Jan. 25, 2009).

18. *See id.*

19. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (holding a new bacterium was produced with different characteristics from any found in nature).

20. *See id.* at 308-09.

21. The Bayh-Dole Act, 35 U.S.C. § 200 (2007).

ther privatize biomedical research.[22] The Act allows universities to patent inventions that result from government-funded research. As a result, over 4,500 firms have developed non-profit research institutes, based on patents generated as a consequence of this law.[23] American universities and institutes grossed $1.39 billion in licensing revenue and applied for more than 10,000 new patents in 2004 alone.[24] Between 1985 and 1995, the United States government invested more than $50 billion in the biological sciences and actively encouraged private-sector investment.[25] This legislation had dramatic economic effects and is extremely controversial to this day.

Another foundational case that set the standard for allowing patenting of altered genetic products was decided in July of 1990 in *Moore v. Regents of the University of California*.[26] In *Moore*, the plaintiff was a patient at the UCLA Medical Center who underwent treatment for hairy-cell leukemia.[27] Before having his spleen removed, one of the doctors gave the surgeons written instructions to have a portion of plaintiff's spleen obtained for research purposes without the knowledge or consent of the plaintiff.[28] After the medical procedure, the plaintiff was told to return to the Medical Center for treatment numerous times, purportedly because it was necessary for his health and well-being.[29] During these follow-up visits, the researchers took additional samples and established a cell line from the plaintiff's T-lymphocytes.[30] The cell line was recognized as commercially valuable because the plaintiff's T-lymphocytes overproduced a particular lymphokine whose corresponding genetic material was easily identifiable, and the researchers later obtained a patent for the specific cell line.[31] Regarding the plaintiff's action for conversion, the court held the plaintiff did not have a property interest in the patented subject matter "because the patented cell line is both factually

22. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698-701 (May 1, 1998).

23. *Bayhing for Blood or Doling out Cash?*, THE ECONOMIST, Dec. 24, 2005, at 109.

24. *Id.*

25. Joseph Fuller & Brock Reeve, *Will We Lose in the Stem Cell Race?*, WASH. POST, Feb. 3, 2007, at A15, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/02/02/AR2007020201525.html?referrer=emailarticle.

26. Moore v. Regents of Univ. of California, 793 P.2d 479 (1990).

27. *See id.* at 480.

28. *See id.* at 481.

29. *See id.*

30. *Id.*

31. *See id.* at 482; U.S. Patent No. 4,438,032 (filed Jan. 6, 1983) (patenting the cell line and the products derived from it).

and legally distinct from the cells taken from Moore's body."[32] The cell line constituted a product of "human ingenuity," not naturally occurring, and patentable because "long-term adaptation and growth of human tissues and cells in culture is difficult . . . and the probability of success is low."[33]

Subsequently, the biotechnology industry experienced an economic boom. From 1992 to 2006, U.S. healthcare biotech revenues from publicly traded companies grew from $8 billion to $58.8 billion.[34] The Human Genome Project ("HGP"), which began in 1990 to identify all the genes in human DNA, was completed in 2003.[35] The completion of the project resulted in an explosion for companies in the private sector, both large and small, who sought to utilize the data gathered by the HGP in a number of different applications.[36] One such biopharmaceutical company was Myriad Genetics, the discoverer of genes BRCA1 and BRCA2, which are involved with DNA damage repair.[37] After the discovery, Myriad Genetics obtained patents for BRCA1, and, more specifically, the methods and materials used to isolate and detect a human breast cancer predisposing gene.[38] Five months later, Myriad Genetics was granted a patent on BRCA2 and its corresponding genetic screening tests.[39] The patents were extremely broad and covered many mutations of the two genes, as well as the use of these mutations for diagnosis and prognosis of breast and ovarian cancer, among other uses.[40] Subsequently, Myriad Genetics was granted a patent by the European Patent

32. *See Moore*, 793 P.2d at 492.

33. *See id.* at 492-93.

34. BIO, Biotechnology Industry Facts, http://www.bio.org/speeches/pubs/er/statistics.asp (last visited Jan. 18, 2009).

35. Human Genome Project Information, http://www.ornl.gov/sci/techresources/Human_Genome/ home.shtml (last visited Jan. 18, 2009).

36. The Human Genome Project & the Private Sector: A Working Partnership, On the Shoulders of Giants: Private Sector Leverages HGP Successes: *Data, Technologies Catalyze a New, High-Profile Life Sciences Industry*, http://www.ornl.gov/sci/techresources/Human_Genome/project/privatesector.shtml (last visited Jan. 18, 2009).

37. Genetic Testing for Hereditary Cancer Syndromes Resource Guide: BRCA1 and BRCA2 Genes, http://www.myriadresourceguide.com/bracanal/genes.htm (last visited Jan. 22, 2009).

38. U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,710,001 (filed June 7, 1995).

39. U.S. Patent No. 5,837,492 (filed April 29, 1996); *see also* Byron Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L. J. 123-46 (2002) (providing a more elaborate explanation of the race to patent BRCA1 and BRCA2).

40. *See* John Murray, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 CHI.-KENT L. REV. 231, 233 (1999).

Office for BRCA1 in January 2001 and for BRCA2 in May 2001.[41] Institutions and society at large became uneasy as genetic engineering rapidly advanced and was assimilated into the medical standard of care. For example, on August 2, 1999, the American College of Medical Genetics ("ACMG") issued a position statement on gene patents and accessibility of gene testing. The institution stated that genes and their mutations are naturally occurring substances that should not be patented, and licensing agreements should not limit patient access through excess royalties and other unreasonable terms.[42]

On March 9, 2000, Myriad Genetics announced that it had exclusively licensed MDS Laboratory Services to make available the BRACAnalysis molecular diagnostic tests to women across Canada who may be at risk of breast and ovarian cancer.[43] Subsequent to this, Myriad Genetics signed exclusive licensing agreements with companies across the globe from Japan[44] to Germany, Switzerland, and Austria.[45] U.S. Representative Lynn Rivers introduced the Genomic Research and Diagnostic Accessibility Act of 2002, which creates an exemption from patent infringement for researchers who use genetic-based diagnostic tests for noncommercial purposes.[46] International organizations held workshops to discuss the proliferation of gene patents and their implications. In January 2002, the Organisation for Economic Co-Operation and Development ("OECD"), an international institution that collects data and monitors trends regarding economic developments,[47] held a

41. European Parliament resolution on the patenting of BRCA1 and BRCA2 ('breast cancer') genes, http://www.cptech.org/ip/health/biotech/eu-brca.html (last visited Nov. 13, 2009).

42. American College of Medical Genetics, Position Statement on Gene Patents and Accessibility of Gene Testing, http://genetics.faseb.org/genetics/acmg/pol-34.htm (last visited Jan. 23, 2009).

43. Myriad Genetics Launches Molecular Diagnostic Testing in Canada, MDS Laboratory Services to Provide BRACAnalysis® Throughout Canada, http://www.corporate-ir.net/ireye/ir_site.zhtml (last visited Nov. 13, 2009).

44. Myriad Genetics Launches Genetic Testing in Japan, Falco biosystems, Ltd. to Promote Myriad's Commercial Products in Japan, http://www.corporate-ir.net/ireye/ir_site.zhtml (last visited Nov. 13, 2009).

45. Myriad Genetics Launches Predictive Medicine Testing in Germany, Switzerland, and Austria, http://www.chemie.de/news/d/3678/ (last visited Jan. 23, 2009).

46. Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002).

47. Organisation for Economic Co-Operation and Development, About OECD, http://www.oecd.org/pages/0,3417,en_36734052_36734103_1_1_1_1_1,00.html (last visited Jan. 25, 2009).

meeting in Berlin, Germany to identify any problems in obtaining legal access to genetic inventions.[48]

Other organizations have tried to provide guidance regarding the emerging issues in genetic engineering. For example, the National Institutes of Health ("NIH"), Public Health Service ("PHS") and Health and Human Services ("HHS") combined efforts in 2004, announcing recommendations regarding the best practices for the licensing of genomic inventions.[49] Their recommendations included carefully distinguishing between inventions requiring exclusive licensing with those that would be best disseminated nonexclusively in the marketplace.[50] The guidelines suggested that patents covering diagnostics should be licensed on a nonexclusive basis, and universities should not patent genomic technologies if significant research and development is unnecessary to get a product to market.[51] The thrust of the guidelines was to target questionable licensing practices that had the potential to inhibit access to genetic information.

In 1998, Andrew Z. Fire and Craig C. Mello discovered a cellular process called RNA interference ("RNAi") whereby short, double-stranded RNA fragments trigger suppression of gene activity through cellular enzymes in a homology-dependent manner.[52] For their discovery, they received the Nobel Prize in Physiology or Medicine in 2006.[53] The discovery of RNAi marked a milestone in genetic engineering, as it has allowed for greater control in regulating gene expressions. RNAi can influence the development of an organism by suppressing protein synthesis.[54] Furthermore, RNAi-like mechanisms keep chromatin condensed and suppress transcription.[55] This realization of greater genetic control has already been utilized in gene therapy and raises the possibility for its use in medical treatments.[56] For example, Deborah Palliser and her colleagues have shown that small interfering

48. *See* Genetic Inventions, Intellectual Property Rights and Licensing Practices (2002), http://www.oecd.org/dataoecd/42/21/2491084.pdf.

49. Best Practices for the Licensing of Genomic Inventions, 69 Fed. Reg. 67747 (proposed Nov. 19, 2004), *available at* http://www.ott.nih.gov/pdfs/69FR67747.pdf.

50. *See id.*

51. Aparna Surendran, *US NIH Draft Guidelines Threaten Diagnostics Sector*, NATURE BIOTECHNOLOGY, May 2004, at 496, *available at* http://www.nature.com.proxy.libraries.smu.edu/nbt/journal/v22/n5/full/nbt0504-496.html.

52. Nobelprize.org, Advanced Information: The 2006 Nobel Prize in Physiology or Medicine, 1-2, http://nobelprize.org/nobel_prizes/medicine/laureates/2006/adv.pdf (last visited Sept. 15, 2008).

53. *Id.*

54. *Id.* at 6.

55. *Id.* at 7.

56. *Id.*

RNAs ("siRNAs") can protect mice from lethal herpes simplex virus 2 infections.[57] Other researchers have shown that a non-human primate's siRNAs can silence apolipoprotein B ("APOB"), the primary component of low-density lipoprotein ("LDL") cholesterol and what is lowered in most medications designed to treat hypercholesterolaemia.[58] The researchers claim that their "findings show clinically relevant RNAi-mediated gene silencing in non-human primates, supporting RNAi therapeutics as a potential new class of drugs" and "the rapid and long lasting silencing of APOB using RNAi may represent a new strategy for reducing LDL-cholesterol in several relevant clinical settings."[59]

In 2006, the biosciences employed 1.3 million people in the United States and generated an additional 7.5 million jobs.[60] The potential dangers of genetic engineering caught the eye of the late science fiction writer Michael Crichton. In November 2006, Crichton published a techno-thriller novel entitled *Next* delving into some of the controversial aspects of genetic engineering and theorizing about the potential implications of such engineering.[61] Crichton did more than publish a fictional book about the implications of gene patenting, however. On September 14, 2006, while speaking to Congressional staff members, Crichton claimed that genes cannot be owned because they are facts of nature, the gene patents are vague, and the patents discourage research and hurt patient care.[62] He purported that gene patents would negatively affect patient care because the patent holder essentially has a monopoly on the patented material and can choose when and how to make the product of gene patenting available and has the power to set the standard fee of associated diagnostic testing and therapeutic treatment.[63] Mounting public concern about the ethical implications of gene patenting reached an apex on February 9, 2007, when U.S. Congressman Xavier Becerra introduced legislation, the Genomic Research and Accessibility Act ("GRAA"), that would prohibit the patenting of human genetic material.[64] Specifically,

57. Deborah Palliser et al., *An siRNA-based Microbicide Protects Mice from Lethal Herpes Simplex Virus 2 Infection*, NATURE, Jan. 5, 2006 at 89.

58. Tracy S. Zimmermann et al., *RNAi-Mediated Gene Silencing in Non-Human Primates*, NATURE, May 4, 2006 at 111.

59. *Id.* at 111, 113.

60. BIO, Biotechnology Industry Facts, http://www.bio.org/speeches/pubs/er/statistics.asp (last visited Jan. 18, 2009).

61. MichaelCrichton.com, Next, http://www.michaelcrichton.com/books-next-history.html (last visited Jan. 18, 2009).

62. MichaelCrichton.com, Genetic Research and Legislative Needs, http://www.michaelcrichton.com/speech-legislativestaffers.html (last visited Jan. 18, 2009).

63. *Id.*

64. *See* Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2(a) (1st Sess. 2007), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h977ih.txt.pdf.

the GRAA sought to ban the patenting of "a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies."[65] More recently, however, the bill has been referred to the Subcommittee on Courts, the Internet and Intellectual Property, which has not pursued it any further.[66]

Most recently, on May 21, 2008, President George W. Bush signed the Genetic Information Nondiscrimination Act of 2008 ("GINA") into law, which imposes certain restrictions on health-care providers for genetic testing.[67] The law amends portions of the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, and the Public Health Service Act.[68] More specifically, GINA prohibits group health plans and health insurers from requesting or requiring an individual to undergo a genetic test.[69] GINA also prohibits the denial of coverage to a healthy individual and prohibits charging a person higher premiums based solely on a genetic predisposition to developing a future disease.[70]

III. The Great Debate: Exploring the Arguments

There is little doubt that genetic engineering will become increasingly important in the years to come. Parents will have the choice to genetically modify their offspring in a myriad of ways. By identifying and analyzing the different arguments advanced by either side and, more importantly, debunking the arguments or theories that do not have merit, society will have a better framework to view these important decisions. The first part of this section will elaborate on the arguments relied on by proponents of gene patenting. The second part will address positions of individuals who oppose gene patenting.

It is important to clarify a misnomer about a patent owner's rights to a gene. Often, people confuse personal property rights and rights granted by a patent. Among the numerous property rights is the "right to use," which entitles an individual to control his or her physical genes and grants them bodily integrity and freedom of person. An individual essentially has real property rights in his or her genes, which is extremely valuable because a person's genes are in essence the makeup of humanity and individuality. An individual's genetic makeup determines the genetic code of his or her offspring and also contributes to the cumulative commercial value of providing

65. *Id.*

66. H.R. 977, The Genomic Research and Accessibility Act, http://www.washingtonwatch.com/bills/show/110_HR_977.html (last visited November 30, 2009).

67. The Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (2008).

68. *Id.* at 883-96.

69. *Id.* at 883.

70. *Id.*

genetic information to further scientific research.[71] A gene patent does not threaten the principle of an individual's rights to their own genes, but merely entitles the patent owner to exclude others from making, using, or selling the physical molecule.[72]

However, some critics overestimate the amount of control a patent holder has in their invention. For example, Congressman Becerra's website states "[t]wenty percent of these genes have already been patented and we have absolutely no say in what those patent holders do with our genes."[73] At the issuance of the patent, the information is freely available for other researchers who are "not prevent[ed] . . . from perceiving, using, and analyzing information about what the DNA sequence is."[74] As such, in no way does the holder have any claim to the integrity of the person.

This argument is mistaken for several reasons. First, the researcher who holds a patent on an individual's cell line does not have the absolute power to compel him or her to undergo further testing or treatment. If one does not wish for his or her blood or tissue to be used for the development of genetic research resulting in a patent, they are under no obligation to consent. Second, a human gene patent is limited to the patentable subject matter as defined by the claims.[75] Due to the complex and technical nature of gene patents that cover a wide range of processes and inventions, the claims made are often narrowly defined, which limits the exclusion to a very precise methodology.[76] Researchers are free to utilize all genetic information in other contexts.[77] Furthermore, the Food and Drug Administration ("FDA") re-

71. Tampering with our future generation using genetic enhancements raises a plethora of ethical issues which will be discussed later.

72. *See* 35 U.S.C. § 271(a) (2006).

73. Xavier Becerra, *Common sense legislation that will end the practice of gene patenting*, http://becerra.house.gov/HoR/CA31/Issues/genepatents.htm.

74. Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of the DNA Sequences*, 49 EMORY L.J. 783, 788 (2000).

75. *See generally* Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: a Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 359-60 (2007) (stating that the overall pressing problem of U.S. patent law is the over-expansive definition of patentable subject matter but that gene patents have had a relatively minor impact in this way).

76. *See generally id.* at 360 (expressing that the legislature should focus on the "wider problem of patents that broadly claim any practical application of fundamental biological discoveries" and that the most problematic patents have primarily not claimed genes or gene-related inventions).

77. *See* Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566-69 (Fed. Cir. 1997) (holding researcher was free to make human PI using a semi-synthetic DNA to yield a cleavable fusion protein because the University failed to provide an adequate written description to the human insulin gene they broadly defined in their patent).

stricts use of gene patents by regulating articles that fall within their jurisdiction. For example, the FDA has exerted jurisdiction over cloning and certain aspects of gene therapy, as well as assisted reproductive technology and stem cell research.[78] Lastly, the right a patent holder has in the invention is limited because the patent expires after twenty years from its earliest filing date.[79] For all of these reasons, the patent holder does not have carte blanche authority to "do what he wants with *your* genes."

A. The Case for Gene Patents

The majority of arguments in support of gene patenting focus on utilitarian justifications. Essentially, proponents argue that patenting genetic sequences, including their derivatives and methodologies, ultimately result in a greater number of benefits to society that outweigh the potential harmful effects.[80] This argument is an excellent starting point because it examines many of the same factors relied on by opponents of gene patenting but reaches an opposite conclusion.[81] Specifically, when applying a utilitarian framework, both sides will examine the economic, medical, and scientific consequences of gene patenting[82] and undergo a risk-utility analysis to determine whether the benefits outweigh the risks.

Initially, it is important to understand the consequences of the patent system and how its regulation of genes affects economic factors and scientific discovery. First, patents are notoriously expensive and often take a long time to obtain. According to one source, a total average cost of patenting a highly complex invention is roughly $15,000 but can go well above that.[83] To put that number in context, another source indicates the average expected charge in 2004 for preparing and filing a utility patent application was $12,373 for a relatively complex biotechnology/chemical application.[84] Aside from the substantial costs, the average patent prosecution, the process a patent application must undergo prior to the issuance of a patent, generally

78. Peter Barton Hutt et al., Food and Drug Law: Cases and Materials 952-60 (3d ed. 2007).

79. 35 U.S.C. § 154(a)(2) (2002).

80. *See* Holman, *supra* note 75 at 360-61.

81. *Id.*

82. Also, many policy concerns and utilitarian arguments focus on agricultural consequences of gene patenting, which is beyond the scope of this article. For an excellent article covering the policy concerns of the consequences of patenting genetic modifications in agriculture *see* Taiwo A. Oriola, *Consumer Dilemmas: The Right to Know, Safety, Ethics and Policy of Genetically Modified Food*, 2002 SING. J. LEGAL STUD. 514.

83. Gene Quinn, *Cost of Obtaining a Patent*, http://www.ipwatchdog.com/patent/patent-cost/ (last visited Jan. 18, 2009).

84. Thomas C. Fiala & John E. Wright, *Preparing and Prosecuting a Patent That Holds up in Litigation*, 875 PLI/PAT 515, 521-22 (2006).

takes three to four years for extremely complex inventions.[85] These figures only reflect the claims that proceed through patent prosecution without obstruction and are subsequently free from litigation. The average estimated cost of litigating a patent in 2005 ranged from $769,562 to $5,175,753, depending on the amount of damages at risk.[86] A different study found that the estimated cost of patent prosecution, maintenance, and management totaled between $20,000 and $30,000 per patent.[87]

Considering the amount of money required to obtain and defend a patent, proponents argue that patents are necessary to protect the holder's investment. Also, the patent system allows the owner to recuperate the costs invested in development of the product by giving the owner a right to exclude all others from the use of the developed product. These positive economic consequences of the patent system in the context of gene patents can be seen more clearly through examples of biotech firms. In February 2007, the New York Times wrote on the struggles and successes of Xoma, Ltd.[88] The article reports that the firm spent more than $700 million since its inception in 1981, without earning a profit or marketing a drug.[89] Medically, its efforts in developing antibody therapeutics have been invaluable, but like many groups that are heavily involved in research and development, the directly marketable product is quite limited. This resulted in high expenses for important and highly utilizable information, but little monetary profit. Another example is Celera Genomics, a biotech firm that spent $200 million per year in research and design investment from 1997 to 2001 without turning a profit.[90]

The fact that many biotech companies struggle to survive illuminates the principle that investors are hesitant to buy into developing biotechnology products that do not receive patent protection.[91] Kevin Noonan, Ph.D., a bio-

85. Bay Area Intellectual Property Group, L.L.C., *Patent Information, Patents, Search, and Invention Development*, http://www.bayareaip.com/Services/PatentApplication/NonProvisionals/NonProvisionals.htm#prosecution (last visited Jan. 19, 2009).

86. Fiala, *supra* note 84, at 522.

87. Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECHNOLOGY 31, 31-39 (2006), *available at* http://www.nature.com.proxy.libraries.smu.edu/nbt/journal/v24/n1/full/nbt0106-31.html#f6.

88. *See* Andrew Pollack, *It's Alive! Meet One of Biotech's Zombies*, N.Y. TIMES, Feb 11, 2007, *available at* http://www.nytimes.com/2007/02/11/business/yourmoney/11xoma.html.

89. *See id.*

90. *See* DAVID B. RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING 67 (2004).

91. Posting of Kevin Noonan to Patent Docs, http://patentdocs.typepad.com/patent_docs/2007/02/science_fiction.html (Feb. 13, 2007, 14:00 CST).

technology patent law expert, explains that unpatented inventions would be hidden as trade secrets or stolen by big companies.[92] The consequences of not providing patent protection include forcing U.S. companies to compete against worldwide corporations who can drastically underpay their employees.[93] Moreover, there is a loss of incentives to follow product development all the way to pharmaceutical success, thereby less pursuit of the production of the next "miracle drug" and less public disclosure and stifling of the large generics industry that relies on the expired patents.[94] Finally, it is important to remember that the biotechnology industry itself has been largely developed by providing businesses with intellectual property rights through DNA patterns.[95] As can be seen by examining the two biotech companies mentioned above, the substantial time and costs required to develop, produce, test, market, and implement a biotech product necessitate a certain amount of patent protection so the company can protect their research and development investment.[96]

Concerning diagnostic uses for gene patents, Adda Gogoris, an expert in biotechnology patents stated:

> Diagnostics are notoriously low-profit-margin products . . . If the right to develop a diagnostic were to be shared by more than one company, the economic incentive to develop it is likely to evaporate. Who would go through the development and approval process only [to compete] with another company for a low-profit market?[97]

Perhaps the most common argument for gene patenting is that the patent system promotes technological progress because it creates incentives for innovation. The United States Constitution specifically gives Congress the right "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[98] Generally, patents are thought to facilitate research by encouraging investment and guaranteeing the holder a way to recoup what is often a substantial initial investment. A paper drafted by the Nuffield Counsel on Bioethics ("NCB") states that "Protection by patents of specific diagnostic tests which are based on DNA sequences could provide

92. *See id.*

93. *See id.*

94. *See id.*

95. *See* RESNIK, *supra* note 90.

96. *See id.*

97. *See* Surendran, *supra* note 51, at 496.

98. U.S. CONST. art. I, § 8, cl. 8.

an effective means of rewarding the inventor while providing an incentive for others to develop alternate tests."[99]

At this time, it is critical to introduce an exception to infringement that gene patenting proponents often raise as it relates to restrictions placed on research. Almost 200 years ago, the Supreme Court created a common law exception to infringement, called the Experimental Use Exception, which courts have frequently applied to academic researchers.[100] The Exception provides relief from a patent infringement claim when the individual "conducted such a machine merely for philosophical experiments, or for the purposes of ascertaining the sufficiency of the machine to produce its described effects."[101] The Experimental Use Exception does not inhibit research because it allows an inventor to utilize the collective academic knowledge to pursue other ends. This doctrine serves as another example illustrating the point that researchers are rarely restricted in their utilization of information, although courts have narrowed the exception significantly.[102]

Proponents of gene patenting argue that researchers articulate the gene-patenting claims so narrowly in order not to inhibit innovation.[103] While examining human gene patent litigation, Christopher Holman draws this same conclusion and breaks down the claims into four categories.[104] Concerning human gene patent litigation involving infringement based on the recombinant production of a therapeutic protein, Holman found only one case where a court found infringement, which resulted from the defendant's use of a native human erythropoietin cDNA sequence the plaintiff's patent broadly claimed.[105] An overall view of his study indicates that courts commonly do not find infringement in the case of human gene patents.[106] Often, the parties to the suit will settle out of court or the court will intervene and order arbitration.[107] Holman concludes that human gene patents have a positive effect on

99. Gaia Vince, *Gene Patents "Inhibit Innovation"*, NEW SCIENTIST, July 23, 2002, *available at* http://www.newscientist.com/article/dn2580-gene-patents-inhibit-innovation.html.

100. *See* Michael S. Mireles, *Adoption of the Bayh-Dole Act in Developed Countries: Added Pressure for a Broad Research Exemption in the United States?*, 59 ME. L. REV. 259, 277-78 (2007).

101. Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

102. *See* Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do University Deserve Special Treatment?*, 57 HASTINGS L. J. 921, 921-23 (2006).

103. *See* Holman, *supra* note 75, at 302-03.

104. *See id.* at 323.

105. *See id.* at 325-26.

106. *See generally id.* at 323-60.

107. *See id.* at 346-58.

the cost and availability of protein therapeutics.[108] Additionally, an empirical study conducted at Georgetown University concluded NIH guidelines, like licensing practices and market forces, influence university practices more than gene patents, which have minimal research-blocking effects.[109]

To summarize, gene patents are a method of reimbursement for the companies, researchers and investors that put up substantial amounts of capital in the hopes of developing a significant pharmaceutical innovation. Patent protection provides security for the investment community who would otherwise not invest in such a traditionally low-profit venture. Similarly, patent protection provides security and incentive to the individual researchers undertaking the work. In reality, the small biotech firm that is supported by substantial capital but still lacks a marketable product is essentially working free of charge until they develop a marketable product, which for some remains an elusive accomplishment. Additionally, patent protection enables the recovery of the large fees often associated with patent prosecution. Also, patents make economic sense regarding genetic testing. Since profit margins on the tests are generally quite low, if companies shared the profits, they would be discouraged from investing substantial amounts. In summary, although the research is admittedly mixed, the latest studies do not support any indication that granting gene patents blocks research efforts.

B. The Case Against Gene Patents

The most common objections to gene patenting can be placed in two broad categories, utilitarian and moral/ethical. Utilitarian objections often involve the effect on the academic community's ability to engage in research or the effect on access to information and testing, while moral/ethical objections primarily focus on the public health policy or the social policy in general. The OECD subdivided the utilitarian arguments into a useful framework whereby research, commercialization, and clinical use issues all fall under the concerns regarding patents procured and limited access to both researchers and patients.[110]

In stark contrast to the claim that gene patenting promotes innovation, opponents maintain the view that patenting of genes actually inhibits innovation. This argument often takes many forms or labels. For instance, in 1998, Michael Heller and Rebecca Eisenberg postulated the paradoxical effect of the privatization of biomedical research called "the tragedy of the anticommons."[111] According to this theory, a resource is prone to underuse when multiple owners each have a right to exclude others from a scarce resource

108. *Id.* at 356.

109. *See* Pressman, *supra* note 87.

110. *See* Genetic Inventions, Intellectual Property Rights and Licensing Practices, *supra* note 48, at 12.

111. *See* Heller, *supra* note 22.

and no one has an effective privilege of use.[112] More specifically, when patent protection is granted, the access to the information is hindered and further research efforts are choked. Efforts are choked because patents are said to increase prices and restrict use because many researchers could hold fragmented patent claims that overlap with one another.[113] The signs of this "anticommons" effect are theorized to be decreased scientific output, rising patent licensing and equipment costs, reduced private sector investment, diminished entry of new scientists and companies, and increased concentration of patent ownership.[114] A patent thicket is a similar term defined as "an overlapping set of patent rights requiring that those seeking to commercialize a new technology obtain licenses for multiple patentees."[115] The result is a failure to further the usefulness of the genetic information through a collective and cooperative academic environment.

The problem with the anticommons argument is twofold: the applicant is required to provide a detailed written description of the invention,[116] and current research has failed to substantiate the claim.[117] Regarding the first reason, information concerning the invention and the manner of designing, producing, and using the invention are completely disclosed to the public. The Supreme Court has interpreted this requirement of disclosure as "the quid pro quo of the right to exclude."[118]

The disclosure requirement has two implications that are important to consider regarding their effect on research. First, the right to exclude others is limited to "the claim language, the written description portion of the specification, the prosecution history, and if necessary to aid a court's understanding of the patent, extrinsic evidence."[119] Due to the technical nature of gene patents, the claims in the applications are extraordinarily detailed regarding the sequence, process, and use. As such, research is generally not prohibited because the right to exclude is limited to the specific claims made in the patent application. For example, in *Genzyme Corporation v. Transkaryotic*

112. *See id.*

113. *See id.*

114. *See* David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1684 (2007).

115. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 Innovation Policy and the Economy 119 (Adam B. Jaffe, Josh Lerner, & Scott Stern eds., 2001), *available at* http://faculty.haas.berkeley.edu/shapiro/thicket.pdf.

116. 35 U.S.C. § 112 (2007).

117. *See* Adelman & DeAngelis, *supra* note 114, at 1685.

118. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974).

119. Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000) (quoting Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1476 (Fed. Cir. 1998)).

Therapies, Inc., Genzyme Corporation was the exclusive licensee of U.S. Patent No. 5,356,804 (the '804 patent).[120] Genzyme sued Transkaryotic Therapies, Inc. alleging patent infringement due to Transkaryotic's use of a process called gene activation where a DNA sequence, acting as a promoter, is inserted into a human host cell.[121] Once inserted, the endogenous human cellular gene encoding á-galactosidase A ("á-Gal A") is activated to express the endogenous human á-Gal A protein.[122] To determine whether Genzyme's patent was infringed, the court looked to two specific claims in the patent application, which stated in relevant part:

> 1. A method for producing human [á-Gal A] comprising: (a) culturing a mammalian cell containing a chromosomally integrated nucleotide sequence encoding human [á-Gal A] controlled by a regulatory sequence that promotes gene expression and a selectable marker controlled by the same or different regulatory sequence, so that the [á-Gal A] nucleotide sequence is stably overexpressed and an enzymatically active [á-Gal A] enzyme is secreted by the mammalian cell; and (b) isolating enzymatically active [á-Gal A] enzyme from the mammalian cell culture. 10. A mammalian cell comprising a chromosomally integrated nucleotide sequence encoding human [á-Gal A] controlled by a regulatory sequence that promotes gene expression and a selectable marker controlled by the same or different regulatory sequence, so that the [á-Gal A] nucleotide sequence is stably overexpressed and an enzymatically active [á-Gal A] enzyme is secreted by the mammalian cell.[123]

The court examined the claims and concluded that Transkaryotic's process of gene activation did not infringe on Genzyme's process because it required the introduction of exogenous sequences encoding á-Gal A into a host cell, a process which Genzyme concedes that Transkaryotic's technique does not utilize.[124] In other words, even though the á-Gal A gene was involved in the patent, that in itself does not preclude other researchers from utilizing, toward an alternate ultimate goal, the information that was freely disseminated as a result of the patent. As such, this patent did not prevent other researchers from utilizing the same exact gene in another method. To the contrary, it is likely that Genzyme's work fostered more research by laying an initial foundation upon which future tiers of investigation could be built.

120. Genzyme Corp. v. Transkaryotic Therapies, Inc., 346 F.3d 1094, 1096 (Fed. Cir. 2003).

121. *Id.*

122. *Id.*

123. *Id.*

124. *See id.* at 1105-06.

Regarding the second problem with the anticommons argument, many researchers have used empirical studies to refute the claim that research is inhibited. In fact, the same paper by the NCB positing that the patent system has advantages simultaneously warns that innovation may be inhibited by increasing the cost of research to other scientists interested in the same sequence.[125] Also, studies conducted from 2002 to 2006 in four countries indicate that anticommons problems are relatively infrequent, despite the large number of patents and interested parties, such as pharmaceutical firms, biotech startups, universities, and governments.[126] Another study that focused on human gene patent litigation also concluded gene patents have had a modest impact in the context of genetic testing and research tools. It determined there is not enough evidence to support the assertion that gene patents inhibit innovation.[127] A different study reached the same conclusion by examining broad patent trends, patterns of patent ownership, and the distribution of patents across PTO patent subclasses.[128] The study indicates that a "lack of concerted control [of patents by large companies,] the rising number of patent applications, and the continuous record of new market entrants provide strong evidence that biotechnology patenting is not adversely affecting innovation."[129] In addition to demonstrating the lack of sufficient evidence to determine the impact of any anticommons effect, the study also indicates that both sides of the debate are oversimplifying the dynamics of patenting practices when they rely on patent count alone.[130]

Another major argument against gene patents concerns questionable licensing practices when holders of a patent grant exclusive licenses to firms. This creates the possibility of abusing a monopoly by charging exorbitant fees for diagnostic testing or associated procedures. This objection to gene patenting touches on its economic consequences and claims that the patents cause increased costs for new testing and treatment. The most widely cited example of this practice is Myriad Genetics. The company entered into commercial agreements with numerous health management organizations and insurance companies across the globe. Critics claim that the broad nature of the European patents, in conjunction with the licensing agreements, create vulnerabilities to patent infringement lawsuits for other clinicians and European laboratories who utilize the new genetic techniques.[131] For example,

125. *See* Vince, *supra* note 99.

126. *See* Timothy Caulfield et al., *Evidence and Anecdotes: an Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1092 (2006).

127. *See* Holman, *supra* note 75, at 359-61.

128. *See* Adelman & DeAngelis, *supra* note 114, at 1681.

129. *Id.*

130. *Id.* at 1729-30.

131. *See* Williams-Jones, *supra* note 39, at 139.

French BRCA testing performed "in-house" would cost approximately a third of Myriad's price; complying with the patents and paying Myriad to process the genetic test would result in an estimated additional $7.6 million cost to hospital budgets.[132] In late 2008, the European Patent Office ("EPO") Appeals Board amended Myriad's patent to limit its scope to cover frame-shift mutations in the BRCA1 gene. While this limitation appears to be a success for other European clinicians, the EPO decision creates uncertainty because, given that the patent only partially covers a diagnostic method, it will be difficult to determine where compliance ends and infringement begins.[133] Regardless of the amendment, critics contend that Myriad's practice of charging high licensing fees will discourage laboratories from providing this very valuable genetic and diagnostic testing where the patent is in force.[134] As a result, there are very few laboratories available and the results can take as long as three to four weeks until they are returned to the clinician. This may exacerbate the already significant unrest and anxiety in the patient who is awaiting such sensitive results.

Another example of questionable licensing agreements and subsequent abuse of a monopoly can be seen in the case of *Greenberg v. Miami Children's Hospital Research Institute, Inc.* Plaintiffs—individuals, families, and institutions interested in curing Canavan disease—brought suit against Miami Children's Hospital ("MCH") for conversion, claiming their financial support led to the breakthrough discovery of the gene responsible for the disease.[135] A patent was issued for that discovery and for its related applications, such as diagnosis of and screening the Canavan disease.[136] The plaintiffs claim they did not know of MCH's intent to obtain a patent and were under the impression that the research would lead to carrier detection and testing, which would be provided on an affordable and accessible basis.[137] At that point, MCH began to threaten enforcement action against the centers offering Canavan testing, claiming they would restrict public access ability through exclusive licensing agreements and the charging of royalty fees.[138] The court held, consistent with *Moore*, that the plaintiffs have no cognizable property interest in body tissue and genetic matter donated for research.[139] Critics view cases like these as evidence of the ill effects of broad gene patents and the injustice that occurs when one entity is able to restrict access to

132. *Id.*

133. *See id.*

134. *Id.*

135. *See* Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003).

136. *See id.*; U.S. Patent No. 5,679,635 (filed Sept. 9, 1994).

137. *See Greenberg*, 264 F. Supp. 2d at 1067.

138. *See id.*

139. *See id.* at 1074-75.

diagnostic and treatment tools that were developed, to some extent, by a community of supporters who pooled resources for the benefit of all. The common fear, and the plaintiffs' cry in *Greenberg*, is that "[patent holders will] beg[i]n restricting public accessibility through negotiating exclusive licensing agreements and charging royalty fees."[140] A separate, but related, argument regarding the high costs of medical testing and treatment is that opponents claim it is unfair for private companies to realize high profits from research that was sponsored and funded by the Government.[141] As discussed above, the Bayh-Dole Act allowed the private sector to take a giant leap in securing intellectual property rights in their products. Opponents argue the Act merely allows private companies to profit from public investments in research. Specifically, one opponent has argued that the Act takes the power away from the Government to negotiate with pharmaceutical companies to provide reasonably priced drugs.[142] The argument relies upon the fact that many medical innovations result from research funded by the public-sector, yet private biotechnology firms reap enormous benefits despite the ever increasing cost of testing and treatment in the United States.[143]

Many objections to gene patents are based on either moral grounds or public policy concerns. Skepticism seems to stem from the idea of a patent covering an inherent part of the human organism. For instance, the human genome has been characterized as a "blueprint of life" by President Bill Clinton on January 27, 2000, in his State of the Union Address.[144] Similarly, the United Nations Educational, Scientific and Cultural Organization (UNESCO) declared that, "[t]he human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent indignity and diversity. In the symbolic sense, it is the heritage of humanity."[145] Genes, by their very nature, are the essence of who we are, and people often object to the fact that a researcher, who has successfully characterized a genetic mutation, is given a patent and thereby appears to somehow have a stake in our physical autonomy. The European Commission's patent laws forbid patents that are contrary to public morality.[146] The Commission considered the issue of whether or not DNA patenting degrades

140. *See id.* at 1065.

141. *See* RESNIK, *supra* note 90, at 69.

142. *See* Merrill Goozner, *The Price Isn't Right*, THE AMERICAN PROSPECT, September 11, 2000, at 25 (providing substantial evidence that government-funded research is responsible for a majority of medically significant knowledge).

143. *See id.*

144. William J. Clinton, Eighth State of the Union Address (Jan. 27 2000).

145. G.A. Res. 152, U.N. Doc. A/RES/53/152 (March 10, 1999).

146. RESNIK, *supra* note 90, at 62; *see also* Article 6, Directive 98/44/EC of the European Parliament and of Council of 6 July 1998 (hereinafter "EPC Article 6"), *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF.

human dignity when the European Patent Convention convened.[147] Conversely, the effects of gene patenting on morality and human dignity are largely absent in United States case law. For example, neither Chief Justice Burger's majority opinion nor Justice Brennan's dissenting opinion in *Diamond v. Chakrabarty* includes any discussion of the moral implications of gene patenting.[148] Essentially, opponents raise a plethora of moral arguments such as: it is morally wrong to allow the patenting of natural things that are created by God; it is repugnant and contrary to public policy to commodify the human body and nature; and DNA is humanity's common property and, as such, it should not be owned by private individuals. Traces of the latter argument can be seen in President Clinton's speech and UNESCO's declaration. One implication of gene patenting that serves as a grounds for objection is the commercialization of the human body. The negative consequences can manifest in different ways. For example, the plaintiff in *Moore* had abnormal T-lymphocytes that produced an abundance of lymphokines, "thus making the corresponding genetic material easier to identify."[149] This made the plaintiff's cells particularly valuable.[150] They were so valuable that the doctors responsible for Moore's health failed to disclose their personal financial motives before harvesting his cells.[151] Aside from unethical conduct, critics also object to this type of commercialization from an evolutionary perspective. They claim that the future of genetic engineering lies in the ability to genetically modify human offspring. What parents, if given the chance to guarantee their future generation is inoculated from the HIV virus, bipolar disorder, Alzheimer's disease, and a host of other genetic disorders, would not do so if financially able? Who would not bolster their children's physical and cognitive abilities? Opponents would say these practices, supported by gene patents, could result in a genetics arms race where the affluent and wealthy have the ability to genetically enhance the next generation while the less fortunate go without such options.

Other objections are seemingly based on both negative publicity and misunderstandings of and about the patent system. Disastrous events obviously adversely impact the public perception of gene patenting. For example, the medical community and the public at large were shocked when on September 17, 1999, 18-year-old Jesse Gelsinger died while undergoing experimental gene therapy at the University of Pennsylvania.[152] Jesse was involved in the gene therapy trial in an attempt to correct or alleviate a genetic

147. *See* EPC Article 6.

148. *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

149. Moore v. Regents of Univ. of Cal., 793 P.2d 479, 482 (Cal. 1990).

150. *See id.*

151. *See id.* at 483.

152. Nicholas Wade, *Patient Dies During a Trial of Therapy Using Genes*, N.Y. TIMES, Sept. 29, 1999, *available at* http://query.nytimes.com/gst/fullpage.html?res=9E06EED8173EF93AA1575AC0A96F958260.

defect that prevented the correct metabolism of ammonia.[153] He, like other participants, was given an infusion of corrective genes, encased in a genetically engineered adenovirus.[154] The doctors speculate that the virus triggered an inflammatory reaction which subsequently caused multiple organ systems to fail.[155] A subsequent investigation by the Food and Drug Administration ("FDA") and the NIH revealed that gene therapy researchers were not following all of the federal rules requiring them to report unexpected adverse events associated with the gene therapy trials.[156] For instance, "researchers entered [Jesse] into the trial as a substitute for another volunteer who dropped out," even though "[Jesse's] high ammonia levels at the time of the treatment should have excluded him from the study."[157] Jesse's death had a chilling effect on gene therapy research as the FDA closed the trial at the University of Pennsylvania, suspended gene therapy trials, and launched random inspections of other clinical trials nationwide.[158] Three years later, officials in the United States and France "suspended four gene therapy experiments because the treatment" may have resulted in a three-year-old boy's acquisition of an illness similar to leukemia.[159] While it is not certain the gene therapy was causally related to the boy's illness, Dr. W. French Anderson, one of the first scientists to use gene therapy to treat severe combined immune deficiency, stated that "gene therapy was likely responsible."[160]

An additional example is Jolee Mohr, who, on July 24, 2007, died from a fungal infection, massive internal bleeding, and organ failure which arose during experimental gene therapy—the goal of which was to determine the safety and potential negative effects of the treatment.[161] Ultimately, investigations by company scientists and an NIH expert panel found no evidence

153. *See id.*

154. Sheryl Gay Stolberg, *The Biotech Death of Jesse Gelsinger*, N.Y. TIMES, Nov. 28, 1999, *available at* http://query.nytimes.com/gst/fullpage.html?res=9C03E4DE1F3CF93BA15752C1A96F958260.

155. *Id.*

156. *See* Larry Thompson, *Human Gene Therapy: Harsh Lessons, High Hopes*, 34 FDA CONSUMER 5 (2000).

157. *See id.*

158. *Id.*

159. *See* Sheryl Gay Stolberg, *Trials are Halted on a Gene Therapy*, N.Y. TIMES, Oct. 4, 2002, *available at* http://query.nytimes.com/gst/fullpage.html?res=9C01E7D9163BF937A35753C1A9649C8B63.

160. *See id.*

161. Rick Weiss, *Death Points to Risks in Research*, WASH. POST, Aug. 6, 2007, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/08/05/AR2007080501636.html.

that the treatment was at fault, and FDA has given the company, Targeted Genetics, permission to resume human testing.[162]

It may be argued that many individuals who are unfamiliar with gene patenting pose objections based on this negative publicity. While advances and breakthroughs are often lauded in academic journals, rarely does that information make headline news. However, when we hear that someone died as a result of experimental gene therapy, suddenly the risks appear more salient than the benefits and people object. The information delivered to the public seems to be inequitably presented. Despite these tragic losses, genetic engineering and gene therapy research is becoming increasingly safer. Researchers at the Massachusetts Institute of Technology have recently created a new polymer that replaces the viruses' former function of delivering experimental gene products into the human body, thereby creating a safer, more immunologically neutral factor for transmission of products.[163] As a result, many of the public concerns are unfounded and essentially amount to "genetic sensationalism."

In summation, opponents of gene patenting claim the practice is resulting in a "tragedy of the anticommons" where patent holders have the same stake in a particular subject matter due to the precise detail required to create a claim and invention.[164] Challengers of gene patenting also argue that researchers will be paralyzed with uncertainty regarding whether they should use the nucleotide sequence or process—they will either be subject to a lawsuit or forced to abandon their efforts entirely, instead directing their research to an area where no patents are held.[165] Critics also claim this patenting process restricts progress, prevents academic cooperation, and frustrates research efforts because patenting genes can restrict access to affordable genetic testing as patent holders are able to exclude other researchers from using their cell line or method.[166] There is also the potential for patent holders to charge any fee they desire, which exacerbates the problem of providing affordable and effective therapy and diagnosis capabilities to the people suffering from the disease, which is ultimately what the discovery was designed to address.[167]

Critics cite Myriad Genetics and Miami Hospital as prime examples of how patent holders can abuse their monopoly by restricting access through

162. Rick Weiss, *Gene Therapy Study Is Allowed to Resume*, WASH. POST, Nov. 26, 2007, at A03, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/11/25/AR2007112501229.html.

163. *See* Katherine Bourzac, *Gene Therapy without Viruses: A New, Highly Effective Polymer May Make Gene Therapy Safer*, TECH. REV. Sept. 12, 2007, *available at* http://www.technologyreview.com/biomedicine/19367/page1/.

164. *See* Heller, *supra* note 22, at 698-701.

165. *See* Williams-Jones, *supra* note 39, at 139.

166. *See id.*

167. *See id.* at 137.

licensing agreements and royalty payments.[168] Opponents also denounce gene patents as morally repugnant and contrary to public policy.[169] These objections emphasize the position that we "should not play God" or trivialize human dignity by turning it into a commodity. Still, perhaps others object based on a limited knowledge or misunderstanding about the patent system and negative news publicity.[170] Some people may conflate owning a gene patent with having ownership rights in one's genes. It is evident that the general public may object to genetic patents on a number of different moral based grounds as a result of "genetic sensationalism."[171] In other words, the public is provided an infinitesimal amount of information that is easy to misinterpret if one is not knowledgeable about the patent laws. What makes matters worse is when respected individuals, such as Michael Crichton, become very vocal about one aspect of the debate which greatly influences many people.[172] The average layperson is not presented with a systematic analysis of the benefits and risks of gene patents and the one-sided bombardment erroneously amplifies public emotion.

IV. Looking Ahead

At this point, it is necessary to reevaluate the arguments, discard the arguments that are based on erroneous assumptions or misconceptions, and analyze the resulting strong positions to determine, among other things, gaps in the existing research and areas in need of improvement. It appears as though a combination of factors has given rise to a certain degree of skepticism and sensationalism regarding gene patenting. Only when the debate is boiled down to its truthful and essential components can society take action to defend against adverse consequences.

Over the years, many multifaceted arguments that have been espoused regarding the moral objections to gene patenting, and a detailed analysis of the many arguments for and against DNA patents is beyond the scope of this article. Certainly, morality should be considered when legislation is being written or passed, in judges' rulings on the bench, and at the forefront of individuals' minds when establishing licensing arrangements. However, the PTO has established that when a genetic sequence is altered, the natural compound becomes a compound that is patentable due to human ingenuity.[173] As such, the USPTO has articulated a standard where a distinction is drawn between an abstract idea and a legitimate and concrete application of an idea.

168. *See id.* at 123.

169. *See id.* at 123-24.

170. *See generally* Wade, *supra* note 152.

171. *See* Mark A. Rothstein, *Genetic Exceptionalism & Legislative Pragmatism*, 35 Hastings Center Report, Issue No. 4, July-Aug. 2005.

172. *See generally* Michael Crichton.com, *supra* note 61.

173. *See Moore*, 793 P.2d at 492-93.

Within this framework, many of the moral arguments seem to lack strength in that they fail to consider the positive and the adverse consequences of gene patenting, and instead, maintain that the practice should not exist. To the contrary, genetic patenting has persisted in the face of legislation attempting to ban the practice and is highly likely to become more prolific.

That being said, morality and ethics play a vital role in how gene patents should be regulated to maximize the benefits to pharmaceutical companies and patients alike. This is especially true when one speculates about the future of genetic modification and enhancement. There appears to be a telescoping nature of technology. It took approximately two billion years for life to exist, six million years for the hominid and 100,000 years for mankind. In more recent times, there is a further time crunch related to technology. 10,000 years for the development of agriculture, 400 years for the scientific revolution in the Renaissance and 150 years for the industrial revolution. There is no doubt that within our lifetime, genetic manipulation will reach a level where parents will be able to safeguard their young through genetic enhancement. It is likely that the modifications will seem innocuous and in violation of either public policy or morality. The modifications will provide a way to prevent the destructive and often hereditary disease of bipolar disorder or alcohol addiction. No one will object to a genetic enhancement that will cure a genetic abnormality. However, what if parents were able to physically or cognitively enhance their unborn children *in utero*? Or, what if they could increase their children's height, improve their reflexes, or even enhance memory? How will these practices be regulated, if at all? This is where ethical considerations play an enormous role. The moral argument is well-placed as the only basis for objection to an extremely useful practice, and it is extremely important for an arbiter to determine to what extent society should continue forward with genetic issues.

Whether a system of DNA patents inhibits or promotes scientific innovation is more unclear. Earlier researchers and scholars thought a network of patents would create an environment where similarly situated holders would be in the position to exclude each other. Heller and Eisenberg suggest two instances where patents may increase the transaction costs of product development, thereby inhibiting scientific research.[174] First, an anticommons effect can be created by creating too many concurrent fragments of intellectual property rights on future products.[175] For example, the authors state the example that a Lexis search of the phrase "adrenergic receptor" disclosed more than 100 U.S. patents with that phrase in the claim language.[176] As such, biotechnology firms will be unable to obtain a complete set of licenses, which would deter the pursuit of that project.[177] The second anticommons

174. *See* Heller, *supra* note 22, at 699.

175. *Id.*

176. *See id.*

177. *See id.*

scenario arises when too many upstream patent owners stack licenses on top of the future discoveries of downstream users.[178] In other words, the use of reach-through licensing agreements could inhibit innovation because the patent holders stack overlapping and inconsistent claims on potential downstream products, essentially giving the patent holder continuing rights, often in the form of a royalty on sales, and exclusive or nonexclusive license on future discoveries, or an option to acquire such a license for future products.[179] However, despite the theoretical plausibility of this theory, the predicted effects have not been found. Moreover, the assertion is not consistent with other studies, relevant case law and available data regarding the concentration of patent control, the yearly number of patent applications, and the amount of investment in the biotechnology industry from the private and public sector. For instance, many other studies have not found the predicted effects to either be nominal or nonexistent.[180]

There has been a history of public outcry concerning gene patenting that continues today. However, the interesting question is, considering the documented effects on research and access to treatment, why do the objections persist? A number of scholars have proposed a solution which merits a brief discussion. The idea posits that the general public and legislators have a tendency to treat genetics as fundamentally different from other biological subject matter, and thus enact gene-specific legislation.[181] This phenomenon, known as "Genetic Exceptionalism," "allows elected officials to avoid difficult issues by enacting genetic-specific laws that seem to respond to a perceived new crisis, but in fact offer little or no protection and may even be counterproductive."[182] One scholar sarcastically stated, "It is not surprising that elected officials would want to avoid fundamental and controversial issues and focus instead on nominally protecting the public against the highly publicized evils of invidious genetic discrimination."[183] This phenomenon relates to the negative publicity argument, or genetic sensationalism, articulated above. Essentially, ill-informed members of the public catch wind of a negative headline related to DNA patents and, being ignorant of the law, feel a sense of urgency and uneasiness. However, after sorting through the mis-

178. *See id* at 699-700.

179. *See id.*

180. *See* Caulfield, *supra* note 126 at 1092 (finding the predicted anticommon effects to be much less prevalent than would be expected).

181. *See generally* Mark A. Rothstein, *Genetic Exceptionalism & Legislative Pragmatism*, HASTINGS CENTER REPORT 35, No. 4, July-Aug. 2005, at 27-33 (arguing genetic-specific laws have limited value in preventing or redressing the harm caused by the uses and disclosures of genetic information); Stephen Fink, *EEOC v. BNSF: The Risks and Rewards of Genetic Exceptionalism*, 42 WASHBURN L. J. 525 (2003).

182. *See id.* at 32-33.

183. *Id.* at 33.

conceptions, it is evident that humanity need not fear that another individual or institution "owns" your genes.

Ideally, the road to improved regulation would be straight and clear and decisions would be based on a detailed risk assessment in which the consequences of DNA patenting are evaluated. However, it is likely that the academic community is still largely ignorant regarding many of the potential harms of gene patenting. Therefore, policy recommendations need be made with the understanding that the regulation should be flexible in order to accommodate newly discovered evidence. After reviewing the literature, many suggestions can be made and discussed in the academic community to mitigate the negative effects of gene patenting while maintaining their benefits. First, something must be done to cut down on the expenses and lengthy delays of patent prosecution. As noted above, the costs of developing a genetically engineered product are costly; it sometimes takes years to go through the patent prosecution process. Perhaps granting an extension to the patent life for the length of time in prosecution, or minimizing the fees required to file, could provide further incentives for innovation and greater security. However, before this suggestion can be implemented, a task force should be created to examine what the effects would be on the generic drug industry. At first blush, the extension of the patents life would cause a manufacturer of generic drugs to delay use of the information, thus the price of the treatment would remain high.

Another option would be to create a subdivision in the FDA specifically to monitor experimental testing facilities to ensure compliance with guidelines. According to the follow-up investigations for the few deaths associated with gene therapy, the testing facilities neglected the required reporting of many mishaps. Whether the institutions conducting the research did not know the federal requirements or had knowledge of the requirements but chose not to comply, there is a necessity for stricter scrutiny and careful documentation in experimental genetics. Another suggestion would be to advise the PTO about the ill effects of granting patents with broad claims, which vests too much control in one holder and hinders research. Also, the PTO and FDA could corroborate and set up special committees within their respective agencies, for the sole purpose of expediting gene patents which have potential applications in clinical diagnosis and treatment. Thus, when a new miracle drug is discovered, it could be brought to the market safely and efficiently to maximize the drug's benefit. Additionally, one scholar has suggested the establishment of an ethics board that sits apart from the patent office and to provide clear guidelines regarding current concerns.[184] To effectuate a speedy process, an ethics board would only accept applications that pose significant ethical questions. The purpose of the board would be to balance the many benefits of genetic patenting and to add an ethical voice to

184. *See* Richard Gold & Timothy A. Caulfield, *The Moral Tollbooth: A Method That Makes Use of the Patent System to Address Ethical Concerns in Biotechnology*, THE LANCET, June 29, 2002, at 2268.

the patent prosecution process. The author notes that such a board should be able to suspend the power to enforce the patent which would provide the flexibility needed to deal with patents that truly raise an ethical concern, while not slowing down the process of patent examination.[185]

Congress could also set up licensing laws for gene patents to protect against potential abuses and foul play, such as enacting legislation to prohibit the number of subleases a patent holder can make in an effort to avoid patent thickets. Furthermore, Congress should codify the "experimental use" exception in patent law and provide a carefully articulated and clear definition so that patent agencies and researchers can better utilize this exception. With the changing administration and the economy in a downslide, the President can encourage private investment in the biotech industry and perhaps provide more federal funding to the research institutions and universities. As an aside, researchers who collect tissue or cell samples should inform the participants of the potential monetary value of the material, as well as any intent to patent DNA sequences. Despite the lack of a requirement that researchers compensate the participants, the disclosure would provide a greater level of informed consent.

Thanks to many scholars, there is ample research regarding the impact of human gene patent litigation,[186] whether those gene patents accorded with the purposes of the United States patent system,[187] and how DNA sequences meet the requirement of utility and are patentable subject matter.[188] However, more research is needed regarding the economics and potential effects that gene patents have on research in the academic and clinical community. The current literature is replete with inconsistent findings, including a lack of repetitive efforts to replicate findings and a lack of a standard on which to measure these effects. Specifically, the finding that the "anticommons tragedy" is uncommon does not mean that research is not being inhibited.[189] The reports indicate "the effects are much less prevalent than would be expected if its hypothesized mechanisms were in fact operating."[190] However, this is merely stating that the effects are a matter of degree. Research still may be inhibited due to the granting of patents and fear of infringement. Moreover, the research should be limited to a specific geographic area. Patenting an invention in one country does not preclude the use of that invention in another country. This is why biotechnology companies are seeking patents from the PTO and the EPO.

185. *See id.*

186. *See* Holman, *supra* note 75.

187. James Bradshaw, *Gene Patent Policy: Does Issuing Gene Patents Accord with the Purposes of the US Patent System?*, 37 WILLAMETTE L. REV. 637 (2001).

188. *See* Villamil, *supra* note 15.

189. *See* Caulfield, *supra* note 126.

190. *Id.*

Since patents are territorial in nature, they should be analyzed individually. After individual countries are analyzed, a meta-analysis can be performed to search for research inhibiting patterns worldwide. However, it is important that statistical analyses do not rely on patent counts alone. Rather, the research should examine the amount of control over patents exerted by large companies, the number of patent applications that are filed each year, as well as the number of patents that are granted, and the amount of companies that are entering the biotechnology industry.

V. CONCLUSION

Despite a tumultuous early history, the patenting of genetic materials and processes is deeply rooted in American jurisprudence and has resisted adverse legislation as well as international warnings. Many of the benefits of gene patenting have been realized to some extent. Since 1992, billions of dollars have poured into the biotechnology industry from public and private sector investment. This explosion of scientific knowledge has created thousands of jobs, spurred research and innovation resulting in an untold number of medical advances, and enhanced academia by creating a close association between public/government institutions and private research firms. Genetic disorders, which were once crippling and/or killing thousands of people, are now curable by relatively simple procedures. Testing procedures have been developed that allow early detection of ailments, thereby increasing the window of treatability and, ultimately, curability.

Unfortunately, the risks of gene patenting have been realized to a much lesser extent. Many historical examples of the negative consequences surrounding gene patenting can be utilized to understand where protection is lacking and how the practice can be regulated more efficiently. For example, scientists are more commonly foregoing the use of viruses as a vector in gene therapy for a safer polymer. But for the unfortunate death of a young man undergoing gene therapy, an alternate form of delivery would not likely have been developed. But for Jessie's death, the FDA and NIH would not have been alerted to the frequent reporting violations and lackadaisical practices by the researchers. In other words, these adverse consequences, albeit tragic, do not support a strong argument for limiting the patenting of genetic material. All scientific innovation would come to a screeching halt if practices were banned that could potentially have adverse consequences. Researchers and scientists can only create regulations to minimize these effects, and when bad results occur, the lessons should be learned from them. The FDA and other industries that can monitor genetic diagnosis and treatment must increase their oversight. These procedures and regulations that attempt to provide protection for the public will provide no value if they are not followed.

In conclusion, the advent of patenting genetic material has raised a myriad of ethical concerns that have been augmented by sensationalism and misconceptions about the law. While they cannot provide strong bases for banning the practice, the ethical objections will play an increasingly important role as genetic modification/enhancement progresses. For now, it is im-

portant to recognize that society has received substantial benefits from research efforts that likely would not have taken place but for patent protection. The most recent research suggests that scientific research is not inhibited, but is actually promoted by granting certain genetic material patent protection. Biotechnology research is an extremely risky venture that often yields no results. To perpetuate and encourage investment and research, patent protection is simply a necessity as a means to an end. Patent protection on biological subject matter creates incentives for the blossoming industry of biotechnology. Reaching the conclusion that patenting genetic material results in more positive consequences than negative, does not mean there should be no limit in the way patent protection can be granted and regulated. Certainly some of these suggestions should be considered in an effort to safeguard human safety and values. The future is uncertain and as human ingenuity grows at an exponential rate, society will face many difficult legal decisions on how far these practices should be extended. Mechanisms such as a separate office within the PTO or an ethics review board should be in place to readily deal with these kinds of decisions.